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**WASHINGTON, D.C. 20460**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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**MEMORANDUM**

**SUBJECT:** **Difenoconazole:** Ecological Risk Assessment for Proposed Label Amendments for Seed Treatment Uses on Potato and Rapeseed Crop Subgroup 20A

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The Environmental Fate and Effects Division (EFED) reviewed the proposed Section 3 label amendments for the fungicide difenoconazole. There are two proposed changes to the Dividend® label: one is the addition of seed-treatment use for potatoes and the other is the expansion of seed-treatment use on canola to include the entire rapeseed crop subgroup 20A. An ecological risk assessment is not needed because application rates of registered uses, as discussed below, account for potential risk resulting from the proposed label changes. The primary potential risk concern from the proposed seed-treatment uses is chronic effects to birds and mammals. The potential dietary risk to bees is unknown due to lack of data and potential for exposure.

The proposed potato seed use is already registered for other difenoconazole products and the proposed application rate of Dividend® on potato seed tubers is the same as that on existing product labels (2.5 g ai/100 kg; USEPA, 2012).

The rapeseed crop subgroup 20A includes canola, which is already registered for Dividend<sup>®</sup>-treated seed at the same application rate as that proposed for the entire crop group. Risk from seed use is typically assessed based on a lb ai/A exposure basis, like most non-seed uses, and also on a mg ai/kg-seed basis, specifically for exposure to birds and mammals that consume seeds. The registered use rate for canola seed in terms of mass ai/seed (242 mg ai/kg seed, *see Appendix A* for calculations; USEPA, 2001) is the same as the proposed use rate for all seed-treatment uses within the rapeseed crop subgroup 20A. Likewise, the application rate in terms of mass ai/A (0.001-0.002 lb ai/A; *see Appendix A* for calculations) is the same for the registered and the proposed use on canola seed. In contrast, some crops within the rapeseed crop subgroup 20A may have a higher amount of active ingredient applied over an acre because the seeding rate (lb seed/A) for these crops is greater than that of canola. For example, the application rate for sesame seed is 0.001 to 0.003 lb ai/A based on seeding recommendations for sesame (5 to 12 lb sesame seed/A) according to a review by the Biological and Economic Analysis Division (BEAD) of extension service recommendations and crop production guides (USEPA, 2011). Although the lb ai/A application rate for the registered use on canola seed is lower than the proposed use on sesame seed, difenoconazole is also registered for foliar use on canola at an application rate that is 38X higher (0.113 lb ai/A; USEPA, 2013) than the highest estimated application rate for sesame seed (*i.e.*, 0.003 lb ai/A). Therefore, environmental exposure from the proposed seed uses is expected to be lower than the registered foliar use on canola given the large difference in application rates. Furthermore, seed treatments generally result in less environmental exposure than foliar applications due to factors other than the application rate (*e.g.*, burying of the treated seed and lack of spray drift). Given these factors, risk from foliar spray applications on canola are protective of the proposed seed uses.

In summary, registered uses of difenoconazole account for potential risk resulting from the proposed label changes. However, the risk conclusions reported in previous risk assessments of related seed-treatment uses do not fully reflect those expected from an updated risk assessment on the proposed seed-treatment uses because they were conducted prior to submission of several toxicity studies, updates to models, and changes to certain policies and guidance. Nonetheless, several risk assessments have been conducted in the interim on uses with higher exposure potential; therefore, those and earlier risk assessments collectively provide an adequate representation of potential risk from the seed-treatment uses. Assumptions about potential risk from the proposed seed-treatment uses were made from a synthesis of the information in the previous assessments (*e.g.*, USEPA, 2001, 2011, 2012, 2014, 2016, and 2017).

First, the primary potential risk concern from the proposed seed-treatment uses is chronic effects to birds and mammals.

Second, it is assumed that there is not a risk concern for aquatic organisms with the possible exception of a potential chronic risk concern for estuarine-marine invertebrates from seed treatments on rapeseed crops in subgroup 20A. There is not a concern for potato seed use because exposure is assumed to be negligible given that the seeds are likely incorporated to a depth of at least 10 cm (Pavek, 2014). Likewise, exposure from rapeseed crop subgroup 20A is expected to be negligible if seeds are planted at depths below 1 inch given the very low application rates. Exposure concentrations would be higher for seeds planted at shallower depths (in the ballpark of those reported USEPA, 2001 and scaled to the application rate of each

proposed crop); however, they are expected to be much lower than those of foliar applications. The potential concern for estuarine-marine invertebrates is primarily due to uncertainty about chronic toxicity (*as discussed in recent risk assessments*), but again there is lower potential for risk from seed-treatment uses compared to the foliar uses given lower application rates, lower potential for runoff with any soil incorporation, and a lack of spray drift.

Third, it is assumed that risk to terrestrial plants is low for the proposed seed-treatment uses. Guideline data were not available at the time of previous risk assessments of these uses; however, they were available at the time of more recent risk assessments of uses with higher application rates. Those assessments indicated a potential risk concern for listed dicot species from run-off. However, risk is less likely for the proposed seed-treatment uses given the lower application rates. For most if not all uses there is some degree of uncertainty about risk to listed dicot species because one of the two tested formulations showed effects to seedling emergence at the limit test application rate; therefore, the level of uncertainty about risk is greater as EECs approach the non-definitive NOAEC (*i.e.*, the limit test application rate). The likelihood of a risk concern for the seed-treatment uses on potato and rapeseed crops is lower than registered foliar uses given that the seed-treatment uses have lower application rates and lower potential for runoff with any soil incorporation. More specifically, the seedling emergence NOAEC would need to be about 35 to 185x lower than the application rate (0.111 lb ai/A) showing effects in the toxicity study.

Finally, risk to honeybees is unknown because dietary toxicity data are unavailable and there is exposure potential in nectar and pollen given that difenoconazole is systemic, the product label indicates that the seed-treatment will control early season foliar diseases (suggesting that uptake into pollen and nectar is possible as well), and the treated crops are attractive to bees (USDA, 2015).

## References

- Pavek, M.J. (2014) Commercial potato production and cultural management. In R. Navarre and M. Pavek (Eds.), *The Potato: Botany, Production and Uses* (pp. 83-102). CPI Group (UK) Ltd.
- USDA, 2015. Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen.
- USEPA, 2001. Ecological Risk Assessment for Section 3 Registration of Difenoconazole as Seed Treatment on Canola. DP 252640.
- USEPA, 2011. Acres Planted per Day and Seeding Rates of Crops Grown in the United States. Biological and Economic Analysis Division (BEAD), Office of Pesticide Programs, United States Environmental Protection Agency.
- USEPA, 2012. Ecological Risk Assessment for the Proposed New Use of Difenoconazole as a Seed Treatment for Potatoes. DP 402993 and 404403.

USEPA, 2013. Ecological Risk Assessment for the Proposed New Use of Difenoconazole on Canola and Oilseed Subgroup 20A. DP 409484 and 409488.

USEPA, 2014. Difenoconazole: Ecological Risk Assessment for Numerous Proposed New Uses and Changes to Registered Uses (Application Rate, Crop Groupings, and Additions to New Products). DP 417610+.

USEPA, 2016. Difenoconazole: Ecological Risk Assessment for Proposed New Uses on Cotton (including Cottonseed Crop Subgroup 20C), Rice, and Wild Rice. DP 432214.

USEPA, 2017. Difenoconazole: Ecological Risk Assessment for Proposed New Uses on Guava, Papaya, Cranberry, and Watercress. DP 435064.

## Appendix A

### Application Rate Calculations for Difenoconazole-Treated Rapeseed Crop Group 20A

#### *Sample calculations for canola*

*(lb ai/A)*

$$0.002 \text{ lb ai/A} = \frac{1.0 \text{ fl oz}}{100 \text{ lb seed}} * \frac{3.1 \text{ lb ai}}{128 \text{ fl oz}} * \frac{740520 \text{ seeds}}{\text{Acre}} * \frac{1.0 \text{ lb}}{90000 \text{ seeds}}$$

*(mg ai/kg seed)*

$$242 \text{ mg ai/kg-seed} = \frac{1.0 \text{ fl oz}}{100 \text{ lb seed}} * \frac{3.1 \text{ lb ai}}{128 \text{ fl oz}} * \frac{1 \text{ lb seed}}{0.4535924 \text{ kg seed}} * \frac{453592.4 \text{ mg ai}}{1 \text{ lb ai}}$$

*Where*

<b>Parameters</b>	<b>Values</b>	<b>Sources</b>
Application Rate (fl oz/100 lb seed)	1	Dividend® label
fl oz/gallon	128	Conversion factor
kg/lb	0.4535924	Conversion factor
mg/lb	453592.4	Conversion factor
Dividend formulation (lb/gallon)	3.1	Dividend® label
Maximum seeding rate (seeds/A)	740520	BEAD <sup>A</sup>
Minimum seeding rate (seeds/A)	435600	BEAD <sup>A</sup>
Minimum numbers of seeds per lb	90000	BEAD <sup>A</sup>
Maximum numbers of seeds per lb	115000	BEAD <sup>A</sup>

<sup>A</sup> Biological and Economic Analysis Division (USEPA, 2011)

#### Estimated Application Rates for Canola

Minimum Application rate (lb ai/A)	0.001
Maximum Application rate (lb ai/A)	0.002